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medicated article or a Type B medicated feed. A Type C medicated feed may be further diluted to produce another Type C medicated feed. The manufacture of a Type C medicated feed from a Category II, Type A medicated article requires a medicated feed mill license application approved under § 515.20 of this chapter.

(5) A Type B or Type C medicated feed manufactured from a drug component (bulk or "drum-run" (dried crude fermentation product)) requires an application approved under § 514.105 of this chapter.

(6) A "veterinary feed directive (VFD) drug" is a new animal drug approved under section 512(b) of the Federal Food, Drug, and Cosmetic Act (the act) for use in or on animal feed. Use of a VFD drug must be under the professional supervision of a licensed veterinarian.

(7) A "veterinary feed directive" is a written statement issued by a licensed veterinarian in the course of the veterinarian's professional practice that orders the use of a veterinary feed directive (VFD) drug in or on an animal feed. This written statement authorizes the client (the owner of the animal or animals or other caretaker) to obtain and use the VFD drug in or on an animal feed to treat the client's animals only in accordance with the directions for use approved by the Food and Drug Administration (FDA). A veterinarian may issue a VFD only if a valid veterinarian-client-patient relationship exists, as defined in § 530.3(i) of this chapter.

(8) A "medicated feed" means a Type B medicated feed as defined in paragraph (b)(3) of this section or a Type C medicated feed as defined in paragraph (b)(4) of this section.

(9) For the purposes of this part, a "distributor" means any person who distributes a medicated feed containing a VFD drug to another distributor or to the client-recipient of the VFD.

(10) An "animal production facility" is a location where animals are raised for any purpose, but does not include the specific location where medicated feed is made.

(11) An "acknowledgment letter" is a written communication provided to a distributor by a consignee who is not the ultimate user of medicated feed containing a VFD drug. An acknowledgment letter affirms that the consignee will not ship such medicated animal feed to an animal production facility that does not have a VFD, and will not ship such feed to another distributor without receiving a similar written acknowledgment letter.

[51 FR 7392, Mar. 3, 1986, as amended at 52 FR 2682, Jan. 26, 1987; 54 FR 51386, Dec. 15, 1989; 56 FR 19268, Apr. 26, 1991; 64 FR 63206, Nov. 19, 1999; 65 FR 76929, Dec. 8, 2000]

**§ 558.4 Requirement of a medicated feed mill license.**

(a) A feed manufacturing facility must possess a medicated feed mill license in order to manufacture a Type B or Type C medicated feed from a Category II, Type A medicated article.

(b) The manufacture of the following types of feed are exempt from the required license, unless otherwise specified:

(1) Type B or Type C medicated feed using Category I, Type A medicated articles or Category I, Type B or Type C medicated feeds; and

(2) Type B or Type C medicated feed using Category II, Type B or Type C medicated feeds.

(c) The use of Type B and Type C medicated feeds shall also conform to the conditions of use provided for in subpart B of this part and in §§ 510.515 and 558.15 of this chapter.

(d) This paragraph identifies each drug by category, the maximum level of drug in Type B medicated feeds, and the assay limits for the drug in Type A medicated articles and Type B and Type C medicated feeds, as follows:

**CATEGORY I**

Drug	Assay limits percent <sup>1</sup> type A	Type B maximum (200x)	Assay limits percent <sup>1</sup> type B/C <sup>2</sup>
Aklomide .....	90-110	22.75 g/lb (5.0%) .....	85-120.
Ampronilum with Ethopabate .....	94-114	22.75 g/lb (5.0%) .....	80-120.
Bacitracin methylene disalicylate .....	85-115	25.0 g/lb (5.5%) .....	70-130.

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Drug	Assay limits percent <sup>1</sup> type A	Type B maximum (200x)	Assay limits percent <sup>1</sup> type B/C <sup>2</sup>
Bacitracin zinc .....	84–115	5.0 g/lb (1.1%) .....	70–130.
Bambermycins .....	90–110	800 g/ton (0.09%) .....	80–120/70–130.
Buquinolate .....	90–110	9.8 g/lb (2.2%) .....	80–120.
Chlortetracycline .....	85–115	40.0 g/lb (8.8%) .....	80–115/70–130.
Coumaphos .....	95–115	6.0 g/lb (1.3%) .....	80–120.
Decoquinate .....	90–105	2.72 g/lb (0.6%) .....	80–120.
Dichlorvos .....	100–115	33.0 g/lb (7.3%) .....	90–120/80–130.
Diclazuril .....	90–110	182 g/t (0.02%) .....	85–115/70–120.
Efrotomycin .....	94–113	1.45 g/lb (0.32%) .....	80–120.
Erythromycin (thiocyanate salt) .....	85–115	9.25 g/lb (2.04%) .....	<20g/ton 70–115/150–50:>20g/ton 75–125.
Iodinated casein .....	85–115	20.0 g/lb (4.4%) .....	75–125.
Laidlowmycin propionate potassium .....	90–110	1 g/lb (0.22%) .....	90–115/85–115.
Lasalocid .....	95–115	40.0 g/lb (8.8%) .....	Type B (cattle and sheep): 80–120; Type C (all): 75–125.
Lincomycin .....	90–115	20.0 g/lb (4.4%) .....	80–130.
Melengestrol acetate .....	90–110	10.0 g/ton (0.0011%) .....	Chickens, turkeys, and quail: 75–125; Cattle: 5–10 g/ton 80–120;
Monensin .....	85–115	40.0 g/lb (8.8%) .....	Cattle: 10–30 g/ton 85–115; Goats: 20 g/ton 85–115; Liq. feed: 80–120.
Narasin .....	90–110	7.2 g/lb (1.6%) .....	85–115/75–125.
Nequinate .....	95–112	1.83 g/lb (0.4%) .....	80–120.
Niclosamide .....	85–120	225g/lb (49.5%) .....	80–120.
Nystatin .....	85–125	5.0 g/lb (1.1%) .....	75–125.
Oleandomycin .....	85–120	1.125 g/lb (0.25%) .....	<11.25 g/ton 70–130; >11.25 g/ton 75–125.
Oxytetracycline .....	90–120	20.0 g/lb (4.4%) .....	75–125/65–135.
Penicillin .....	80–120	10.0 g/lb (2.2%) .....	65–135.
Poloxalene .....	90–110	54.48 g/lb (12.0%) .....	Liq. feed: 85–115.
Ractopamine .....	85–105	1.8 g/lb (0.4%) .....	80–110.
Salinomycin .....	95–115	6.0 g/lb (1.3%) .....	80–120.
Semduramicin .....	90–110	2.25 g/lb (0.50%) .....	80–110.
Tiamulin .....	113.4 g/lb, 100–108 5 and 10 g/ 1b, 90–115	3.5 g/lb (0.8%) .....	90–115.
Tylosin .....	80–120	10.0 g/lb (2.2%) .....	70–130.
Virginiamycin .....	85–115	10.0 g/lb (2.2%) .....	75–125.
Zoalene .....	92–104	11.35 g/lb (2.5%) .....	70–130.

<sup>1</sup> Percent of labeled amount.

<sup>2</sup> Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limits, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make Type C medicated feed.

**CATEGORY II**

Drug	Assay limits percent <sup>1</sup> Type A	Type B maximum (100x)	Assay limits percent <sup>1</sup> Type B/C <sup>2</sup>
Ampronil .....	94–114	11.35 g/lb (2.5%) .....	80–120.
Apramycin .....	88–112	7.5 g/lb (1.65%) .....	80–120.
Arsanilate sodium .....	90–110	4.5 g/lb (1.0%) .....	85–115/75–125.
Arsanilic acid .....	90–110	4.5 g/lb (1.0%) .....	85–115/75–125.
Carbadox .....	90–110	2.5 g/lb (0.55%) .....	75–125.
Carbarsone .....	93–102	17.0 g/lb (3.74%) .....	85–115.
Clopidol .....	94–106	11.4 g/lb (2.5%) .....	90–115/80–120.
Famphur .....	100–110	5.5 g/lb (1.21%) .....	90–115/80–120.
Fenbendazole .....	93–113	8.87 g/lb (1.96%) .....	75–125
Halofuginone hydrobromide .....	90–115	272.0 g/ton (.03%) .....	75–125.
Hygromycin B .....	90–110	1,200 g/ton (0.13%) .....	75–125.
Ivermectin .....	95–105	1,180 g/ton (0.13%) .....	80–110.
Levamisole .....	85–120	113.5 g/lb (25%) .....	85–125.
Maduramicin ammonium .....	90–110	545 g/ton (.06%) .....	80–120.

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**CATEGORY II—Continued**

Drug	Assay limits percent <sup>1</sup> Type A	Type B maximum (100x)	Assay limits percent <sup>1</sup> Type B/C <sup>2</sup>
Morantel tartrate .....	90–110	66.0 g/lb (14.52%) .....	85–115.
Neomycin .....	80–120	7.0 g/lb (1.54%) .....	70–125.
Oxytetracycline .....	80–120	10.0 g/lb (2.2%) .....	65–135.
Neomycin sulfate .....	80–120	100 g/lb (22.0%) .....	70–125.
Nicarbazin (granular) .....	90–110	5.675 g/lb (1.25%) .....	85–115/75–125
Narasin .....	90–110	5.675 g/lb (1.25%) .....	85–115/75–125
Nicarbazin (powder) .....	98–106	5.675 g/lb (1.25%) .....	85–115/80–120
Nitarsone .....	90–110	8.5 g/lb (1.87%) .....	85–120.
Nitromide .....	90–110	11.35 g/lb (2.5%) .....	80–120.
Sulfanitran .....	85–115	13.6 g/lb (3.0%) .....	75–125.
Nitromide .....	90–110	11.35 g/lb (2.5%) .....	85–115.
Sulfanitran .....	85–115	5.65 g/lb (1.24%) .....	75–125.
Roxarsone .....	90–110	2.275 g/lb (0.5%) .....	85–120.
Novobiocin .....	85–115	17.5 g/lb (3.85%) .....	80–120.
Pyrantel tartrate .....	90–110	36 g/lb (7.9%) .....	75–125.
Robenidine .....	95–115	1.5 g/lb (0.33%) .....	80–120.
Ronnel .....	85–115	27.2 g/lb (6.0%) .....	80–120.
Roxarsone .....	90–110	2.275 g/lb (0.5%) .....	85–120.
Roxarsone .....	90–110	2.275 g/lb (0.5%) .....	85–120.
Aklomide .....	90–110	11.35 g/lb (2.5%) .....	85–120.
Roxarsone .....	90–110	2.275 g/lb (0.5%) .....	85–120.
Clopidol .....	94–106	11.35 g/lb (2.5%) .....	80–120.
Bacitracin methylene disalicylate .....	85–115	5.0 g/lb (1.1%) .....	70–130.
Roxarsone .....	90–110	2.275 g/lb (0.5%) .....	85–120.
Monensin .....	90–110	5.5 g/lb (1.2%) .....	75–125.
Sulfadimethoxine .....	90–110	5.675 g/lb (1.25%) .....	85–115/75–125.
Ormetoprim (5/3) .....	90–110	3.405 g/lb (0.75%) .....	85–115.
Sulfadimethoxine .....	90–110	85.1 g/lb (18.75%) .....	85–115/75–125.
Ormetoprim (5/1) .....	90–110	17.0 g/lb (3.75%) .....	85–115.
Sulfathethoxypyridazine .....	95–105	50.0 g/lb (11.0%) .....	85–115.
Sulfamerazine .....	85–115	18.6 g/lb (4.0%) .....	85–115.
Sulfamethazine .....	85–115	10.0 g/lb (2.2%) .....	80–120.
Chlortetracycline .....	85–115	10.0 g/lb (2.2%) .....	85–125/70–130.
Penicillin .....	85–115	5.0 g/lb (1.1%) .....	85–125/70–130.
Sulfamethazine .....	85–115	10.0 g/lb (2.2%) .....	80–120.
Chlortetracycline .....	85–115	10.0 g/lb (2.2%) .....	85–125/70–130.
Sulfamethazine .....	85–115	10.0 g/lb (2.2%) .....	80–120.
Tylosin .....	80–120	10.0 g/lb (2.2%) .....	75–125.
Sulfanitran .....	85–115	13.6 g/lb (3.0%) .....	75–125.
Aklomide .....	90–110	11.2 g/lb (2.5%) .....	85–120.
Sulfanitran .....	85–115	13.6 g/lb (3.0%) .....	75–125.
Aklomide .....	90–110	11.2 g/lb (2.5%) .....	85–120.
Roxarsone .....	90–110	2.715 g/lb (0.60%) .....	85–120.
Sulfanitran .....	85–115	13.6 g/lb (3.0%) .....	75–125.
Aklomide .....	90–110	11.2 g/lb (2.5%) .....	85–120.
Roxarsone .....	90–110	2.27 g/lb (0.5%) .....	85–120.
Sulfaquinoxaline .....	98–106	11.2 g/lb (2.5%) .....	85–115.
Sulfathiazole .....	85–115	10.0 g/lb (2.2%) .....	80–120.
Chlortetracycline .....	85–125	10.0 g/lb (2.2%) .....	70–130.
Penicillin .....	80–120	5.0 g/lb (1.1%) .....	70–130.
Thiabendazole .....	94–106	45.4 g/lb (10.0%) .....	>7% 85–115; <7% 90–110. 85–115.
Tilmicosin .....	90–110	18.2 g/lb (4.0%) .....	

<sup>1</sup> Percent of labeled amount.

<sup>2</sup> Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limit, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make a Type C medicated feed.

(e) When drugs from both categories are in combination, the Category II requirements will apply to the combination drug product.

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.4, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

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